Amendment Attorney Docket No. S63.2B-10941-US01

## Remarks

This Amendment is in response to the Office Action dated July 26, 2006.

Claims 1-9 and 38-42 have been cancelled without prejudice in view of the restriction requirement made Final in the Office Action of 7/26/2006.

Claims 26-28 "elongation at yield" has been changed to "elongation at yield" to conform to the specification disclosure at page 7, lines 23-27. The amendment of claim 32 has been made to conform to the "elongation at yield" antecedent in claim 26.

Claims 10-37 are under consideration and have been rejected. Reconsideration is requested.

Rejection under 35 USC §112

Claim 15 has been rejected as being indefinite as to whether or not an additional step was being recited. Claim 15 has been amended to positively recite the additional steps of providing the tubing segment as a parison for a catheter balloon and forming a catheter balloon from said parison. Withdrawal of this rejection is therefore requested.

Rejections under 35 USC §102

Claims 10-12, 14, 18, and 20-22 have been rejected as anticipated by Pepin et al, US 5,614,136, when taken with Chen et al, US 6,905,743, the Office Action asserting that Pepin et al's variable drawing inherently produces different orientation. "Drawing rate" has been deleted from claim 10 and adjustments of the referenced antecedents have been made as appropriate in the claims depending therefrom. Pepin et al does not teach to vary the gap length, or the cooling rate of the cooling region. Therefore this rejection has been overcome as to claims 10-12, 18, and 20-22.

As to claim 14, the claim has been amended into independent form, including the recitations of original claim 10 and further reciting forming a catheter shaft from the segment. In that context the previously recited proximal and distal regions are not arbitrary, as asserted in the Office Action, and must be given weight for purposes of examination. In particular, when producing the Pepin et al tubing, drawing is used to thin the tubing. When the shaft is orientated as a catheter shaft, that thinning occurs distally. To the extent that the resulting shaft has a variable orientation, the orientation will be higher on the side of the higher draw rate, which is the thinned distal region. Thus Pepin et al cannot be asserted to teach, expressly or inherently,

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production of a catheter shaft that has a higher longitudinal molecular orientation in the proximal region relative to the orientation of the shaft in the distal region. Therefore the rejection of claim 14 has been overcome.

Claims 23-25 have been rejected as anticipated by Pepin et al, US 5,614,136, taken with Chen et al, US 6,905,743. The rejection is traversed. Claim 26 has been amended to specifically recite that a balloon is formed from the slated portions of the parison. Pepin et al does not teach formation of a parison for forming a medical device balloon in which portions of the parison are slated to form cone and waist portions of the balloon and a portion is slated to form the balloon body. In order to slate portions of a tubing segment in such way a tubing segment must be sized in relation to a balloon mold or other balloon forming apparatus. With particular regard to Pepin et al's Fig. 7, cited in the Office Action, the respective portions of the tubing depicted in that Figure 7 have been slated, as catheter shaft proximal sections (30), transitional sections (31) and distal sections (32). No sections are indicated as balloon parisons, no slated portions of the tube are slated to become part of a balloon, and no balloon is formed. Withdrawal of this rejection is therefore respectfully requested.

Claims 26-28, 30, 31, 35 and 37 have been rejected as anticipated by Pepin et al, US 5,614,136, when taken with Chen et al, US 6,905,743. "Drawing rate" has been deleted from claim 26 and adjustments of the referenced antecedents have been made as appropriate in the claims depending therefrom. Pepin et al does not teach to vary the gap length, or the cooling rate of the cooling region. Therefore this rejection has been overcome.

Rejections under 35 USC §103

Claims 15-17 have been rejected for obviousness from Pepin et al, US 5,614,136, in view of Wand, US 5,525,388, when taken with Chen et al, US 6,905,743. The rejection is seen to be overcome by the amendment to claim 10 from which claims 15-17 depend.

Claim 13 has been rejected for obviousness from Pepin et al, US 5,614,136, in view of Di Luccio et al, US 4,720,384, when taken with Chen et al, US 6,905,743. The rejection is traversed. Di Luccio, discussing tubing extrusion, at col. 8, lines 41-45, states:

In the preferred downward extrusion, an airgap is provided between the die and the bath so as to give a slight neck-in. This gap can vary between 0 and a few inches, depending on the properties desired in the final product.

This is clearly teaching that the gap can be chosen according to the properties

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desired in the <u>final product</u>. It says nothing at all about varying the gap along the length of an extrusion to produce different properties at different locations of the extruded tube. A combination of Pepin et al and Di Luccio et al. if proper, might arguably lead one to set a tank gap in the range of between 0 and a few inches, and at the same time vary the draw rate during extrusion to thin some regions relative to others, but it does not lead one to change the gap length along the length of the extruded tube. At least for this reason the rejection should be withdrawn.

Claim 19 has been rejected for obviousness from Pepin et al, US 5,614,136, in view of Tiernan et al, US 6,579,484, when taken with Chen et al, US 6,905,743. The rejection is traversed. The rejection is seen to be overcome by the amendment to claim 10 from which claim 19 depends.

Claim 29 has been rejected for obviousness from Pepin et al, US 5,614,136, in view of Di Luccio et al, US 4,720,384, when taken with Chen et al, US 6,905,743. The rejection is traversed. As previously noted Di Luccio et al leads to a selection of a tank gap, according to desired properties, not to alteration of the gap length during extrusion. At least for this reason the rejection should be withdrawn.

Claims 33-34 have been rejected for obviousness from Pepin et al, US 5,614,136, in view of Wang et al, US 5,556,383, when taken with Chen et al, US 6,905,743. The rejection is seen to be overcome by the amendment to claim 26 from which claim 33 and 34 depend.

Claim 36 has been rejected for obviousness from Pepin et al, US 5,614,136, in view of Tiernan et al, US 6,579,484, when taken with Chen et al, US 6,905,743. The rejection is traversed. The rejection is seen to be overcome by the amendment to claim 26 from which claim 36 depends.

New claims

New claims 43-45 are not inherently met by Pepin et al because they require selection of the recited extrusion parameter(s) on the basis of elongation properties of the different regions. Pepin et al does not teach or suggest to select extrusion parameters on the basis of elongation properties of the different segments. Pepin selects on the basis of a thickness difference. Difference in elongation between regions provides an alternative basis for selection of extrusion conditions and will be advantageous, for instance if thickness variation is not desired or where it is an insufficient indicator for the desired property profile of the respective tubing

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segments.

Conclusion

In view of the foregoing amendments and remarks, the application is believed to be in condition for allowance. Early and favorable action thereon is requested.

Respectfully submitted,

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